

We Claim:

1. A device for use in monitoring a swab method, the device includes a first substrate substantially adjacent a second substrate, the first substrate and the second substrate having disposed therebetween a test material.
2. A device according to claim 1, wherein the test material includes a predetermined amount of test analyte.
3. A device according to claim 2, wherein the test analyte includes any one or more of ATP, a protein, other chemical materials (such as adenosine diphosphate (ADP), adenosine monophosphate (AMP) pyrophosphate (PPi), guanosine triphosphate (GTP), guanosine diphosphate (GDP), guanosine monophosphate (GMP), cytidine triphosphate (CTP), cytidine diphosphate (CDP), cytidine monophosphate (CMP), deoxyribonucleic acid (DNA), ribonucleic acid (RNA), various minerals (including Ca, Zn, Mg, Mn and Co), sugars (including lactose, glucose and maltose), lipids and fatty acids, microbial cell wall and cell membrane materials (such as peptidoglycan, teichoic acid and lipopolysaccharides), enzymes (such as proteases, adenylate kinase, invertase, melibiase, and alkaline phosphatase) and/or a micro organism.
4. A device according to any preceding claim, wherein test material is protected from the environment prior to use, thereby substantially reducing (or preferably substantially inhibiting) contamination of the test material by the external environment.
5. A device according to any preceding claim, wherein the first substrate and the second substrate are sealed together (typically by use of an hermetic bond) substantially at their periphery so as to form a pouch or sachet, the test material preferably being substantially contained in the pouch.
6. A device according to claim 5, wherein the bond is formed by use of an adhesive (such as a polyurethane adhesive), or by means of heat sealing the first substrate and/or the second substrate, or by use of a pressure sensitive adhesive.
7. A device according to any preceding claim wherein the first substrate and the second substrate are coextrusion laminated.
8. A device according to claim 7, wherein the first substrate and/or the second substrate are formed from ethylene vinyl acetate, ethylene methacrylate or ethylene vinyl alcohol.

9. A device according to any of claims 1 to 6, wherein the first substrate and the second substrate are manufactured from a metal, including aluminum (such as aluminum foil), or a plastics material.

10. A device according to any preceding claim, wherein the first substrate and the second substrate are formed from the same sheet of material, preferably the sheet may be folded about a fold-line, the fold-line forming a sealed edge of the pouch.

11. A device according to any preceding claim, wherein the first substrate and the second substrate have respective (internal) surfaces which have different wetting properties, preferably the first substrate has a surface which is hydrophobic and the second substrate has a surface which is hydrophilic.

12. A device according to claim 11, wherein the test material disposed between the first substrate and the second substrate will preferentially wet the hydrophilic surface leaving the hydrophobic surface substantially unwetted.

13. A device according to claim 11 or 12, wherein the test material includes a hydrophilic surface enhancer, such as a detergent, which increases the probability of the test material wetting the hydrophilic surface as opposed to wetting the hydrophobic surface, preferably the hydrophilic surface enhancers include benzalkonium chloride, benzethonium chloride and chlorhexidine gluconate.

14. A device according to any preceding claim, wherein the test material includes a stabilizing agent, such as a chelating agent when the test material includes ATP (the non-enzymic breakdown of ATP is inhibited by chelating divalent cations), (preferably ethylene diamine tetraacetic acid (EDTA)).

15. A device according to claim 14, wherein the stabilizing agent includes a compound which reduces water availability (for example glycerol) therefore improving protein stability when the test material includes a protein.

16. A device according to claim 14, wherein the stabilizing agent includes a quaternary ammonium detergent or biguanide, such as a benzethonium chloride or chlorhexidine gluconate when the test material includes a micro-organism.

17. A device according to any preceding claim, suitable for use in monitoring the Swab method in an ATP assay and protein-based hygiene test, wherein the test material includes a blend comprising:

Glycerol	50g
Chlorhexidine gluconate	2g
Bovine serum albumin	0.5g
ATP	0.18x10 ⁻⁹ g
De-ionized water	50g

18. A device according to claim 17, wherein the test material has a thickness on the first substrate less than about 1 mm, preferably less than about 0.3 mm.

19. A device according to any preceding claim, wherein the first substrate includes a first release portion and the second substrate includes a second release portion, each release portion being arranged about a peripheral edge of the respective substrate, preferably the first release portion being substantially not connection to the second release portion.

20. A method of manufacturing a device, for use in monitoring a swab technique, the method including providing a first substrate, applying a test material to a portion of the first substrate, covering at least the test material on the first substrate with a second substrate, and joining the second substrate to the first substrate so as to encapsulate the test material between the first substrate and the second substrate.

21. A method according to claim 20, wherein the test material is applied to the first substrate as a (relatively) dry, localized spot, (which is particularly preferred) or as a homogeneously applied film.

22. A method of monitoring a swab technique, which method includes:

a) providing a device comprising a first substrate substantially adjacent a second substrate, the first substrate and the second substrate having disposed therebetween a test material including a predetermined amount of an analyte;

b) swabbing the test material with a swab; and monitoring the amount of analyte present on the swab in step (b).

23. A method according to claim 22, wherein the test material is disposed between the first substrate and the second substrate under aseptic conditions.